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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,339	03/12/2004	James W. Voegelé	END-5241	9931

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EXAMINER

ROY, ANURADHA

ART UNIT PAPER NUMBER

3736

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,339	VOEGELE, JAMES W.	
	Examiner	Art Unit	
	Anuradha Roy	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,21-32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,21-32 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Applicant has added new claims 21-34 to the examination. However, claim 33 is missing. Examiner requests Applicant make the appropriate corrections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 21-24, 26-32, & 34 rejected under 35 U.S.C. 102(b) as being anticipated by Wardle et al. (US Publication No. 2002/0120211).

Regarding claim, Wardle et al. discloses a biopsy device comprising:

a hollow sleeve (14) adapted to receive a tissue piercing element (12) therein, the sleeve comprising an open proximal end, a distal end (Figure 1), a sidewall extending between the proximal end and the distal end (wall of 14), and a tissue receiving opening (22 & 28) disposed intermediate the proximal end and the distal end, wherein the tissue receiving opening is formed laterally in the sidewall (Figure 1);

and at least one electrode disposed on the sleeve (20).

In regards to claim 2, Wardle et al. discloses a biopsy device, wherein at the sleeve has an open distal end (16).

With regard to claim 3, Wardle et al. discloses a biopsy device, wherein at least one electrode (20) is associated with the tissue receiving opening (22).

With respect to claim 4, Wardle et al. discloses a biopsy device comprising at least two electrodes (20, 102, 114).

With respect to claim 5, Wardle et al. discloses a biopsy device comprising first and second electrodes associated with the edges of the tissue receiving opening (Figure 5D).

Regarding claim 6, Wardle et al. discloses a sleeve further comprising a connector (34) for releasably attaching the sleeve to a biopsy device.

In regards to claim 7, Wardle et al. discloses a device, wherein the at least one electrode is operatively connected to a source of electrical energy (38).

Regarding claim 21, Wardle discloses a biopsy device comprising:

a hollow sleeve (14) comprising a proximal end, a distal end, and an unitary sidewall extending from the distal end to the proximal end (Figure 1), and a lateral opening (22) formed through a portion the unitary sidewall, wherein the lateral opening is configured to receive tissue, wherein the sleeve is configured to axially receive a portion of a biopsy probe instrument (12); and

one or more electrode (20 & 114) associated with the sleeve.

In regards to claim 22, Wardle et al. discloses a device, wherein the lateral opening (22) is located proximal of the distal end of the sleeve (Figure 1), wherein a portion of the sleeve separates the lateral opening from the distal end of the sleeve.

Regarding 23, Wardle et al. discloses a biopsy device, wherein a portion of the sidewall extends unitarily from the proximal end of the sleeve to the distal end of the sleeve (Figure 1).

With respect to claim 24, Wardle discloses a device further comprising a connector (34) operable to selectively couple the sleeve with the biopsy probe instrument

Regarding 26, Wardle discloses a device wherein the biopsy probe instrument has a tissue receiving window (22), wherein the sleeve is configured such that the lateral opening of the sleeve permits communication of tissue through the lateral opening of the sleeve and through the tissue receiving window of the biopsy probe instrument when the sleeve is coupled with the biopsy probe instrument (Figure 1).

In regards to claim 27, Wardle et al. discloses a biopsy device wherein the biopsy probe instrument is configured to communicate electrical signals to the electrodes [0054] when the sleeve is coupled with the biopsy probe instrument.

Regarding claim 28, Wardle et al. discloses a device wherein the electrodes are configured to receive communication of electrical signals for a power source independent of the biopsy probe instrument [0054].

In regards to claim 29, Wardle et al. discloses a device wherein the one or more

electrodes comprises a longitudinal electrode positioned along the sidewall (114).

Regarding claim 30, Wardle et al. discloses a device where the one or more electrodes comprises an annular electrode position at the distal end of the sleeve (20).

In regards to claim 31, Wardle et al. discloses a device wherein the one or more electrodes comprises a pair of electrodes separated by an electrode gap (space between 20 or space between 114, Figure 6B).

Regarding claim 32, Wardle et al. discloses a device wherein the distal end of the sleeve is open (16).

In regards to claim 34, Wardle et al. discloses a biopsy device comprising:

a biopsy probe instrument (12), wherein the biopsy probe instrument comprises a cutter, wherein the cutter (20) is operable to sever a tissue sample;

a hollow sleeve (14) coaxially positionable external to the cutter, wherein the hollow sleeve comprises a sidewall (sidewall of 14) and an lateral opening (22) formed through a portion of the sidewall, wherein the opening is configured to permit tissue to pass though the sidewall of the sleeve for the tissue to be severed by the cutter; and

one or more electrodes (20 & 114), wherein the one or more electrodes are associated with one to both of the biopsy probe instrument or the hollow sleeve.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al in view of Quick et al. (US Publication No. 2004/0167427).

Regarding claim 25, Wardle et al. discloses a biopsy device with all of the aforementioned element. However, Wardle et al. does not disclose a device, wherein the biopsy probe instrument comprises a distal end having a knife tip, wherein the sleeve is configured such that the knife tip extends distally from the distal end of the sleeve when the sleeve is coupled with the biopsy probe instrument. Quick et al., however, does disclose a device, wherein the sleeve comprises of a knife tip (14). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Quick et al. to incorporate a knife tip with Wardle et al. in order to facilitate tissue severing.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 21-32, & 34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is 571-272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 9:00am and 4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR


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